

**REMARKS**

Upon entry of the present Amendment, Claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68, and 69 will be pending. In this response, claims 1, 12, 22, 62, 63, 64 and 65 are amended and previously-pending claims 3, 4, 13, 14, 24, 25, 66, and 67 are canceled, without prejudice, to clarify the subject matter Applicant regards as his invention.

Claim 1 is amended to incorporate the limitation of claims 3 and 4, which are canceled. Claim 12 is amended to incorporate the limitation of claims 13 and 4, which are canceled. Claim 22 is amended to incorporate the limitations of claims 24 and 25, which are canceled. Claim 65 is amended to incorporate the limitations of claims 66 and 67, which are now canceled.

More specifically, claims 1, 12, 22, and 65 are amended to recite a patch in which the backing comprises a copolymer film, in which the copolymer is a copolymer of a polyester and a polyether, and a hydrogel that comprises a preservative. Support for these amendments is found in canceled claims 3, 13, 24, and 66 as well as at page 19, lines 7-17 and in Example 1 (at p. 29 line 29 through page 30, line 10) of the specification as filed. Claims 1, 12, 22, and 65 are further amended to recite that the backing displays a moisture vapor transmission rate (MVTR) value within the range of from about 500 to about 5000 g/m<sup>2</sup>/d. Support for this amendment is found in the specification as filed at page 18, lines 18-23.

In view of the amendments noted above, Claim 62 is amended to depend on claim 1, rather than on claim 4, which is now canceled, Claim 63 is amended to depend on claim 12, rather than on claim 14, which is now canceled, and Claim 64 is amended to depend on claim 22, rather than on claim 25, which is now canceled.

All of the amendments are supported by the specification as filed. No new matter is added by the amendments to the claims.

**The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are rejected as allegedly obvious over U.S. 6,469,227 (“’227 patent”) in view of U.S. 5,143,071 (“’071 patent”) for the reasons provided in Section 1 pp. 2-3 of the Office Action mailed September 20, 2005 (“the Office Action”).

Claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 are also rejected as allegedly obvious over U.S. Patent Application Pub. No. US 2003/0037833 (“’833 publication”) in view of U.S. 5,143,071 (“’071 patent”) for the reasons provided in Section 2 pp. 3-5 of the Office Action mailed September 20, 2005 (“the Office Action”). Applicant respectfully traverses these rejections.

The legal standard for *prima facie* obviousness requires that three criteria be met: (1) the prior art, either alone or combination, must teach or suggest each and every limitation; (2) a suggestion or motivation in the cited references or in the art to modify or combine the cited references; and (3) the cited references must provide a reasonable expectation of successfully achieving the claimed invention. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Wilson*, 165 U.S.P.Q. 494, 496 (CCPA 1970).

When carrying out an obviousness analysis, it must be kept in mind that the mere listing of elements or attributes of elements that may be discovered or alleged in the prior art, without more, simply amounts to “hindsight reconstruction ... using the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.” (*Grain Processing v. American Maize-Products* 5 USPQ2d 1788, 1792 (Fed. Cir. 1992) (citation and internal quotation omitted). In fact, in response to such defective analyses, the Court of Appeals for the Federal Circuit has “made it clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine the prior art references.” (*In re Dembiczak* 50 USPQ2D 1614, 1617 (Fed. Cir. 1999)).

Specifically, the Court of Appeals for the Federal Circuit has provided that

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the

applicant's disclosure. (*In re Vaeck* 20 USPQ2d 1438, 1442) (Fed. Cir. 1991) (internal citations omitted)

In view of these standards and for the reasons provided below, Applicant respectfully submits that the pending claims are not obvious under § 103 over the '227 patent, the '833 application, or the '071 patent either alone or in combination with one another.

**The Rejections Under 35 U.S.C. § 103  
Over U.S. 6,469,227 In View of U.S. 5,143,071 and  
Over Patent Application Pub. No. US 2003/0037833 In View of U.S. 5,143,071  
Should Be Withdrawn**

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At pages 2-3 of the Office Action, the Examiner noted that the '227 patent does not disclose a sterile patch and does not disclose a hydrogel comprising either of Applicant's recited level of PVP or Applicant's recited preservatives. The Examiner also asserted that the '071 patent remedies the deficiencies of the '227 patent by disclosing a hydrogel comprising 5-35% PVP and by disclosing specific preservatives for inclusion in the hydrogel. Furthermore, the Examiner has alleged that it would have been obvious for one skilled in the art to combine the teaching of the '227 patent with that of the '071 patent and arrive at Applicant's invention.

At pages 3-5 of the Office Action, the Examiner noted that the '833 publication does not disclose a sterile, packaged patch and does not disclose a hydrogel comprising either of Applicant's recited levels of PVP and local anesthetic or Applicant's recited preservatives. The Examiner then asserted that the '071 patent remedies the deficiencies of the '833 publication and that it would have been obvious for one skilled in the art to combine the teaching of the '833 publication with that of the '071 patent and arrive at Applicant's invention.

Primarily for the reasons set forth in Applicant's paper filed July 5, 2005, which are hereby incorporated by reference, Applicant maintains his position that it would not have been obvious, absent guidance provided by the instant disclosure, to combine and modify the teaching of the '227 and '071 patents or the teaching of the '833 publication and the '071 patent, *i.e.* selecting individual elements from each reference and then assembling them in the manner required, in order to arrive at Applicant's invention.

Notwithstanding that position, in response to the Examiner's rejections and in order to expedite allowance of the instant application, Applicant notes that the present claims are directed

toward a sterile patch that comprises a breathable backing that displays an MVTR value within the range of from about 500 to about 5000 g/m<sup>2</sup>/d and that comprises a copolymer film, in which the copolymer is a copolymer of a polyester and a polyether ("a polyester/polyether copolymer film). This presently-claimed patch further comprises a cross-linked polyvinylpyrrolidone-based hydrogel that comprises from about 5% to about 35% by weight PVP and that contains a preservative and from about 0.5% to about 20% by weight of a local anesthetic. The pending claims are also directed toward a package containing Applicant's sterile patch as well as toward a method for inducing local anesthesia comprising topical application of the presently-claimed patch to a mammal. As noted below, the cited art does not disclose Applicant's backing material much less the combination of that backing material with the recited hydrogel to provide Applicant's claimed patch.

The need in the art that was identified by Applicant was for a patch that could be used to treat pain associated with non-intact-skin conditions, *e.g.* ulcers and burns. However, Applicant recognized that, *inter alia*, the desired patch would have to be sterile and would have to be breathable to prevent infection (*see* p. 2, ll. 24-30; p. 3, ll. 1-10; and p. 4, ll. 18-30 of the application as filed). That need was addressed, in one embodiment of the invention, by the presently-claimed patch that includes, in one aspect, the recited breathable backing that displays a moisture-vapor-transmission rate within the range of about 500 to about 5000 g/m<sup>2</sup>/d and that comprises a polyester/polyether copolymer film (*see* p. 18, ll. 11 to 25; p. 19, ll. 3-17; and Section V (Examples) at p. 29, l. 28 through p. 32, l. 2 of the application as filed). The patch of this embodiment of Applicant's invention further comprises a cross-linked polyvinylpyrrolidone-based hydrogel, that comprises from about 5% to about 35% by weight polyvinylpyrrolidone, and from about 0.5% to about 20% by weight of a local anesthetic or a pharmaceutically acceptable salt thereof, as well as a preservative.

Applicant submits that none of the '227 patent, the '833 application, and the '071 patent disclose a patch that with a breathable backing that comprises a polyester/polyether copolymer film, much less the presently-claimed sterile patch that comprises a breathable backing that comprises a polyester/polyether copolymer film and that displays an MVTR value within the range of from about 500 to about 5000 g/m<sup>2</sup>/d and that comprises the recited cross-linked polyvinylpyrrolidone-based hydrogel containing a local anesthetic and a preservative. Moreover,

Applicant respectfully submits that the '227 patent, the '833 publication, and the '071 patent, even in combination, cannot be construed as suggesting the presently-claimed patch and the use thereof.

In contrast to the presently-claimed invention, the disclosure of the cited art is primarily directed toward applications where, for example, infections are not a primary concern, *i.e.* toward relief of topical discomfort (*e.g.* an itch) ('227 patent), toward a conductive, “non-stringy” adhesive for attaching electrodes to skin surfaces ('071 patent), and toward compositions comprising a monohydric alcohol and a penetration enhancer that provide a more rapid onset of local anesthesia (the '833 application). Thus not only do these references not disclose the presently-claimed patch and its specifically-recited backing material, they cannot be construed as suggesting modification of any materials disclosed in that art in an attempt to arrive at Applicant's claimed invention. This is so because each is directed toward a use or problem in which infection, and the importance of sterility, breathability, and inclusion of a preservative, are neither fully appreciated nor fairly disclosed. Moreover, there is no teaching or suggestion in the cited art that would lead one of ordinary skill to Applicant's presently-claimed invention while attempting to practice or optimize the disparate and distinct inventions alleged in the '227 patent, '833 application, or '071 patent.

Accordingly, Applicant submits that the cited art cannot be construed as providing any suggestion or motivation to modify any element disclosed therein in order to arrive at the presently claimed invention. To do so would require gleaning knowledge available only in Applicant's disclosure in an attempt to guide one of ordinary skill to the presently-claimed invention, which would be improper (*In re McLaughlin* 443 F.2d 1392, 1395 (CCPA 1971)).

In view of the above, Applicant respectfully submits that the cited art neither teaches nor suggests every element of the presently-claimed invention, much less the combination of the recited backing and recited cross-linked hydrogel. Moreover, for the reasons provided above, the cited art does not provide any motivation that would lead one of ordinary skill to modify the teaching of the '227 patent, the '833 application, and the '071 patent in an attempt to arrive at the presently-claimed invention. Since the cited art neither discloses every element of the claimed invention and does not provide motivation to modify the teaching of that art, there cannot be any reasonable expectation of success in formulating and using Applicant's non-obvious patch.

Therefore, Applicant respectfully submits that claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68, and 69 are not obvious under 35 U.S.C. § 103 over '227 patent in view of the '071 patent or over the '833 application in view of the '071 patent. Accordingly, Applicant respectfully requests that the rejection of claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68, and 69 under 35 U.S.C. § 103 be withdrawn.

### **Summary**

As noted above previously-pending claims 3, 4, 13, 14, 24, 25, 66, and 67 are canceled. Accordingly the rejection of those claims is now moot and Applicant respectfully requests that the rejection of claims 3, 4, 13, 14, 24, 25, 66, and 67 under § 103 be withdrawn.

For the reasons provided above, Applicant respectfully submits that claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68, and 69 are not obvious under § 103 over either the '227 patent or the '833 application in view of the '071 patent. Accordingly, Applicant also respectfully requests that the rejection of claims 1, 5, 6, 12, 15, 16, 22, 26, 27, 55, 56, 59-65, 68, and 69 under § 103 be withdrawn.

**Conclusion**

Applicant respectfully submits that each ground for rejection of the pending claims has been overcome or obviated. Accordingly, Applicant respectfully requests that the rejection of claims 1, 3-6, 12-16, 22, 24-27, 55, 56, 59-69 under 35 U.S.C. § 103 be withdrawn.

Applicant submits that the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

The Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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